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(54) Nasal Tamponade

(57) Known nasal tamponades which incorporate an inflatable bag suffer from the disadvantage that they cause a high pressure to be transmitted to relatively small areas of the nose defining the nasal cavity and the post-nasal space. The nasal tamponade of the present invention permits a low pressure to be transmitted over a large percentage of the surface regions defining the nasal cavity and post-nasal space, thereby reducing the likelihood of any damage to tissue, and comprises a single inflatable bag 5 which when inflated, even outside a nasal cavity and an associated post-nasal space, generally conforms to the shape of the combination of a nasal cavity and an associated post-nasal space, the bag 5 being formed of a medically acceptable flexible material readily capable, when inflated in the nasal cavity and post-nasal space, of generally conforming to said shape whilst accommodating any irregularities in the surface regions defining the nasal cavity and post-nasal space, so that a major portion of the external surface of the bag 5 may abut the internal surface regions defining the nasal cavity and post-nasal space; and a tube 1 which whilst being flexible is less flexible than the material of the bag 5 and which extends through the bag 5, the tube 1 being provided with one or more port 6 opening into the bag 5 so that on introduction of a gas along the tube 1 the bag 5 becomes inflated, and the tube 1 being suitable to assist in introducing the bag 5 when deflated into the nasal cavity and post-nasal space.

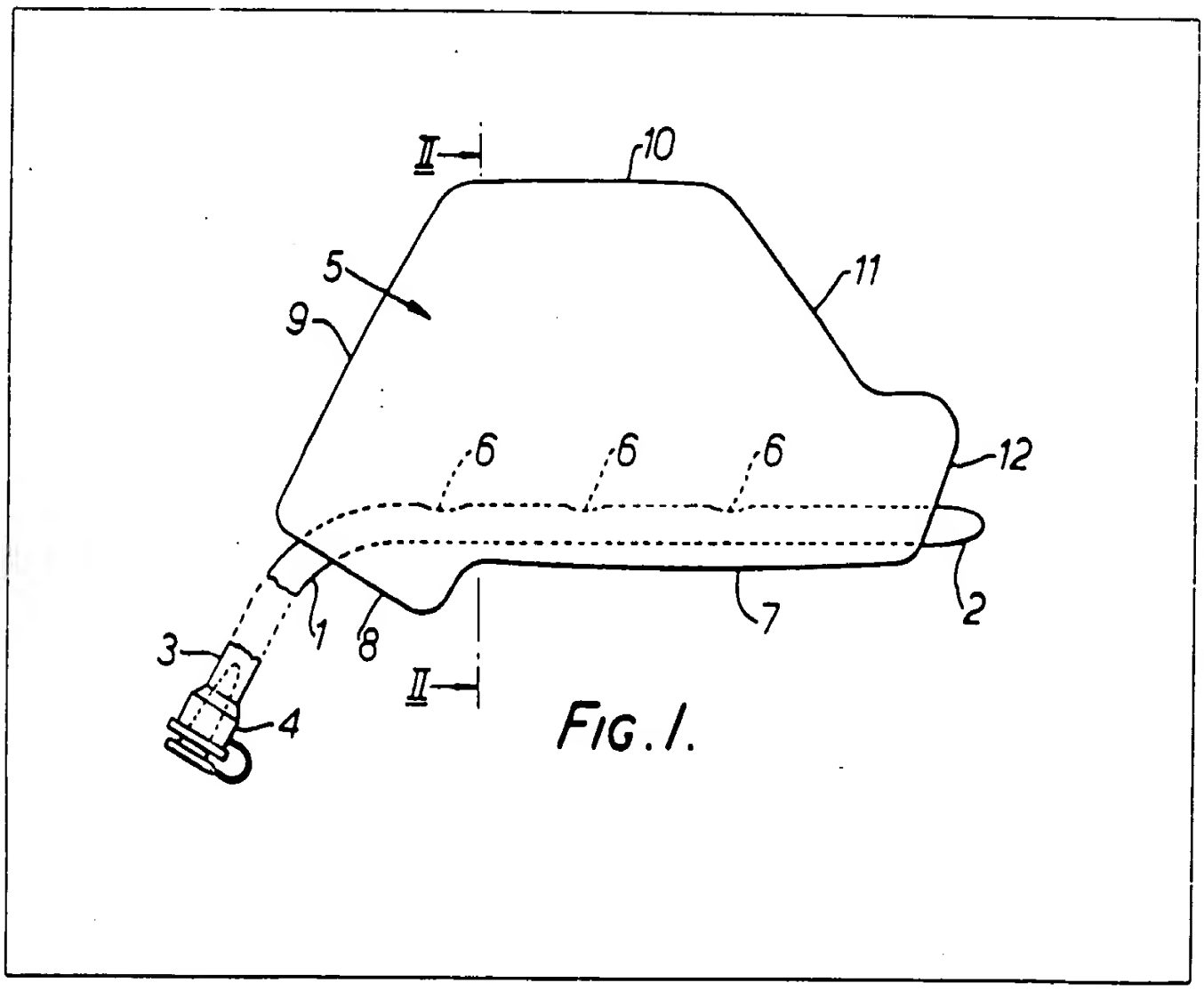

FIG. 1.

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England

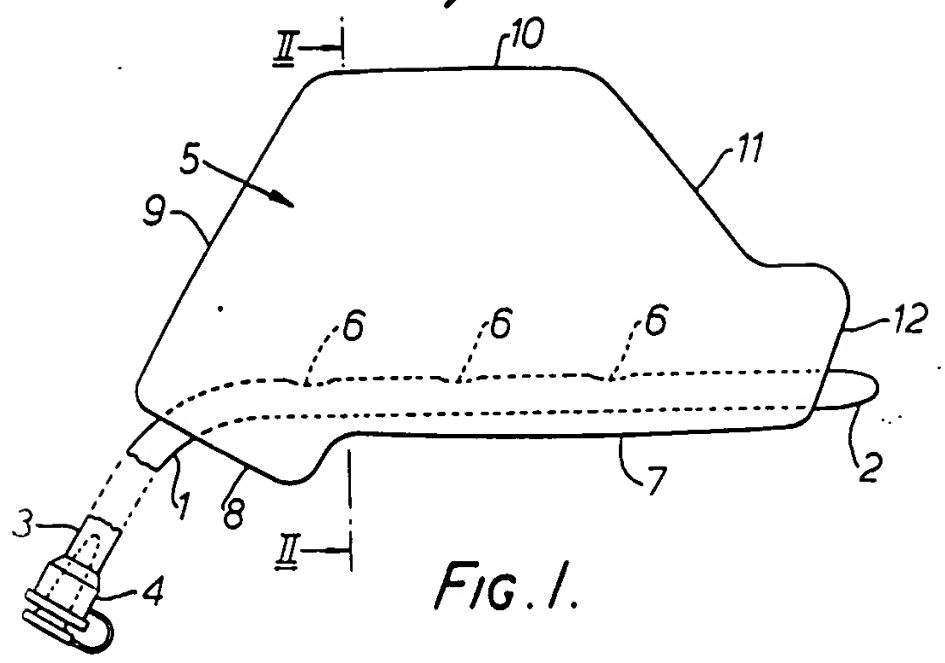

FIG. 1.

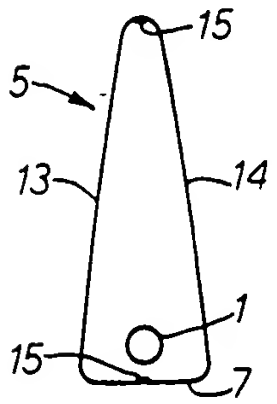

FIG. 2.

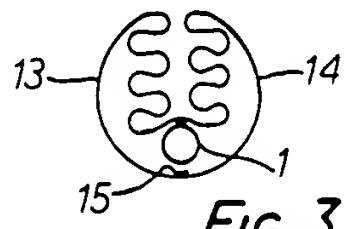

FIG. 3.

SPECIFICATION

Nasal tamponade

This invention relates to a nasal tamponade, which is a means for filling a nasal cavity.

Currently, there are two possible approaches which can be adopted, for filling a nasal cavity. The first possible approach is to pack the nasal cavity with medicated ribbon gauze, but experience has shown that such gauze packing is often most traumatic to the nasal mucosa, thus causing considerable discomfort to the patient. Not only is the introduction of gauze painful to the patient, but different areas of the gauze can press with uneven pressure against the mucosal lining inflicting damage in regions of high pressure; moreover, withdrawal of a nasal gauze pack, even if previously lubricated, is likely to cause the patient considerable discomfort on account of it adhering to the nasal mucosa, and bleeding may even recommence.

The second possible approach is to use an inflatable bag, such as that known as Simpson's nasal bag. However, all known nasal bags appear when inflated to be of generally circular cylindrical cross-section over a majority of their length. In addition, known inflatable bags are formed of a material which, whilst being flexible, is nonetheless rather stiff when inflated to the recommended volume on account of that volume being greater than the residual volume of the balloon. Consequently when such a known inflatable bag is located in a nasal cavity or a post-nasal space a considerable pressure is required in order to cause part of the bag to abut a surface region of the nasal cavity or post-nasal space. This high pressure is transmitted through the bag to the internal surface regions of the nasal cavity or post-nasal space abutted by the bag, with the result that considerable damage to the tissue in these internal surface regions can be caused.

Furthermore in a bag of low residual volume adequately inflated, conformity to an irregular surface is limited by the tension in the wall of the bag and this will result in localised regions of high pressure where the bag makes contact.

According to the present invention, there is provided a nasal tamponade which comprises an inflatable bag which when inflated generally conforms to the shape of the combination of a nasal cavity and an associated post-nasal space, the bag being formed of a medically acceptable flexible material readily capable, when inflated in the nasal cavity and post-nasal space, of generally conforming to said shape whilst accommodating any irregularities in the surface regions defining the nasal cavity and post-nasal space, so that a major portion of the external surface of the bag may abut the internal surface regions defining the nasal cavity and post-nasal space; and a tube which whilst being flexible is less flexible than the material of the bag and which extends through the bag, the tube being provided with one or more port opening into the bag so that on introduction of a gas along the tube the bag becomes inflated, and the tube being suitable to assist in introducing the bag when deflated into the nasal cavity and post-nasal space.

As indicated above, the inflatable bag of the nasal tamponade according to the present invention is formed of a medically acceptable material, and for this purpose a medical grade polyvinyl chloride having a thickness of about 0.02 millimetres is suitable.

The most satisfactory shape of the inflatable bag of the tamponade of the present invention has been arrived at by original anatomical study.

A principal feature of the bag is that it has, compared with known bags used as nasal tamponades, a high residual volume and therefore a low sealing pressure which will be evenly distributed throughout the interior of the nasal cavity, thereby avoiding undue tension in the wall of the bag; this contrasts with the aforementioned known inflatable bags which are of relatively low volume capacity and which require considerable pressure for inflation, which high pressure is transmitted to the areas of contact, thereby causing tissue damage and in extreme cases even perforation of the nasal septum.

Whilst the absolute dimensions of the nasal tamponade according to the present invention will depend upon the size of the nasal cavity and post-nasal space of the patient, the intention is that the bag of the tamponade of the present invention should, when inflated at a modest pressure, occupy the substantial majority of the nasal cavity and post-nasal space. Thus the area of the surface region of the nasal cavity and post-nasal space abutted by the bag of the tamponade of the present invention is considerably greater than that abutted by known inflatable bags of the type mentioned above.

It is also to be appreciated that, because of a lack of tension in the wall of the bag of the tamponade of the present invention, the contact with the nasal mucosa is soft whereas the contact when using other known devies of the type indicated above will be relatively hard.

The bag of the tamponade of the present invention, on account of its particular properties, will be able to conform more readily to the irregularities in the surface region of the nasal cavity much better than will inflatable bags of conventional design; in particular, it is intended that the inflatable bag of the tamponade of the present invention will be able to conform readily to those surface regions of the turbinates which face the nasal septum.

Because of the thinness of the material from

which the inflatable bag of the tamponade of the present invention is formed, and because of its flexibility, the introduction of the tamponade (with the bag collapsed) into the nasal cavity and post-nasal space, and the withdrawal therefrom of the tamponade of the present invention, should be effected without undue discomfort to the patient, as the bag, when in a collapsed condition, need occupy only a small volume.

As regards the tube which forms part of the nasal tamponade of the present invention, the size can be related to the dimensions of the bag but, for intended use with an adult patient, a tube having an external diameter of 5 millimetres has proved suitable. the tube needs to be flexible so as not to aggravate the internal surface of the nasal cavity and post-nasal space, and yet needs to be sufficiently rigid to assist in introducing the bag into the nasal cavity and into the post-nasal space.

The tube can be provided in that end region remote from the bag with a closure system which may optionally include a one-way valve permitting air to be introduced into the bag, and yet which can be overcome by reattaching a syringe to permit the air to be withdrawn from the bag prior to removal of the tamponade from the nasal cavity and post-nasal space.

For a better understanding of the present invention and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings in which:

Figure 1 is a side view of one embodiment of a nasal tamponade according to the present invention;

Figure 2 is a sectional view taken along the line II–II in Fig. 1, with the inflatable bag of the tamponade partially inflated; and

Figure 3 is a sectional view also taken along the line II–II in Fig. 1, but with the bag deflated and folded in on itself to provide a small cross-section suitable for introduction.

In the drawings there is shown a flexible, but not too flexible, tube 1 which is sealed at one end 2 and is provided at the other end 3 with a valved plug 4. That half of the tube 1 adjacent the closed end 2 is enclosed within a sealed bag 5, and apertures 6 in that part of the tube 1 enclosed by the bag 5 provide communication between the interior of the tube and the interior of the bag 5.

As can be seen in Fig. 1, the bag 5 has, as seen in profile, a first base region 7 leading to an adjacent second base region 8 which is inclined in the zone where the tube 1 enters the bag 5 to an inclined front region 9 which at its upper end turns into an upper region 10 which leads to what can be regarded as a scalloped region 11 which in turn leads to a rear region 12 which, in the zone of the closed end 2, turns into the first base region 7.

The right hand end portion (as seen in Fig. 1) of the first base region 7, the rear region 12 and the right hand end portion of the scalloped region 11 constitute that part of the bag which, in practice, is to occupy and thus block the post-nasal space, the remainder of the bag being intended to occupy in use the nasal cavity.

As can be seen from Fig. 2, a vertical section through the tamponade taken in a plane perpendicular to the axis of the tube 1 shows that the bag, under slight inflation, has a generally triangular configuration, with the relatively small base region 8 and two relatively long side wall panels 13 and 14. The bag can be formed from two mirror image portions which are joined by a heat weld 15, there also being an adequate weld/seal in the zone where the tube 1 enters the bag and in the zone where the closed end 2 of the tube just passes through the rear region 12 of the bag 5.

As has been made clear above, the tube 1, whilst being flexible, is nonetheless considerably more rigid than the bag 5 so that, in use, the tube 1 can serve as an introducer for introducing the tamponade into the nasal cavity and post-nasal space. To effect this the upper region 10 of the bag is, with the bag deflated, pushed down towards the tube 1 so that the side panel 13 and 14 bow outwards and upwards as shown in Fig. 3; in practice, one of the curved limbs shown in Fig. 3 will be tucked under the other of the curved limbs shown in Fig. 3 so that an article of relatively small cross-section is produced for introduction into the opening at the front of the nose. Once adequately inserted into the nose, with the closed end 2 of the tube 1 well into the post-nasal space, air or some other gas is passed through the valve 4, via a syringe, along the tube and, via the apertures 6, into the interior of the bag 5, thus causing the latter to inflate. A low pressure will suffice to cause the bag to inflate and to press gently against a high percentage of the internal surface of the nasal cavity and post-nasal space, thereby avoiding any relatively small area, high pressure contact points which could damage the tissue. In order to avoid the creation of an excessive pressure within the bag 5, the pressure of the gas being introduced into the bag 5 can be monitored by a pressure-measuring device; alternatively, the valve plug 4 might incorporate an arrangement which prevents the further introduction of air or other gas once a predetermined pressure has been achieved.

It will be appreciated that the bag, when inflated, conforms to the combination of the nasal cavity and associated post-nasal space, in contrast to known devices serving as nasal tamponades.

In order to withdraw the tamponade from the nose, the pressure is released and the bag

collapsed by appropriate actuation of the valved plug 4 by sucking the air out with a syringe, thus allowing the bag 5 to deflate, after which the tube 1 and bag 5 can be withdrawn from the nose.

CLAIMS

1. A nasal tamponade which comprises a single inflatable bag which when inflated, even outside a nasal cavity and an associated post-nasal space, generally conforms to the shape of the combination of a nasal cavity and an associated post-nasal space, the bag being formed of a medically acceptable flexible material readily capable, when inflated in the nasal cavity and post-nasal space, of generally conforming to said shape whilst accommodating any irregularities in the surface regions defining the nasal cavity and post-nasal space, so that a major portion of the external surface of the bag may abut the internal surface regions defining the nasal cavity and post-nasal space; and a tube which whilst being flexible is less flexible than the material of the bag and which extends through the bag, the tube being provided with one or more port opening into the bag so that on introduction of a gas along the tube the bag becomes inflated, and the tube being suitable to assist in introducing the bag when deflated into the nasal cavity and post-nasal space.

2. A nasal tamponade according to claim 1, wherein the inflatable bag is formed of a medical grade polyvinyl chloride.

3. A nasal tamponade according to claim 2, wherein the polyvinyl chloride which forms the inflatable bag has a thickness of about 0.02 mm.

4. A nasal tamponade according to claim 2, wherein the polyvinyl chloride which forms the inflatable bag has a thickness of about 0.2 mm.

5. A nasal tamponade according to any preceding claim, wherein the tube has an external diameter of about 5 mm.

6. A nasal tamponade according to any preceding claim, wherein the tube is provided, in that end region remote from the bag, with a closure system which may optionally include a one-way valve permitting air to be introduced into the bag, and yet which can be overcome by reattaching a syringe to permit the air to be withdrawn from the bag prior to the removal of the tamponade from the nasal cavity and post-nasal space.

7. A nasal tamponade according to claim 1, substantially as hereinbefore described with reference to, and as illustrated in, the accompanying drawing.

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